

### **REMARKS**

Reconsideration and removal of the grounds for rejection are respectfully requested.

Claims 1-43 were in the application, claims 1-23, 27, 28 and 43 were previously withdrawn in response to a restriction requirement. Claim 24 has been amended, and claims 31, 32 and 33 have been cancelled.

Entry of this amendment after final is respectfully requested as placing the application in condition for allowance and/or reducing the issues on appeal. Entry is proper in accordance with MPEP 714.12:

“Any amendment that will place the application either in condition for allowance or in better form for appeal may be entered. Also, amendments filed after a final rejection, but before or on the date of filing an appeal, complying with objections or requirements as to form are to be permitted after final action in accordance with 37 CFR 1.116(b)”

The amendment to claim 24 overcome the rejections under 35 USC 112, first and second paragraph, by substituting the term “ingestible” for “non-pharmaceutical”, as will be discussed more fully below. Claim 24 has also been amended to clarify the nature of the source, target and egg laying farm animal, all of which were in claim 24, and so no new search nor new issues are raised by this amendment, and such clarification is believed to render moot the remaining rejection. Consequently, entry of this amendment will resolve all outstanding issues, and place the claims in condition for allowance.

Claims 29-26 and 29-42 were rejected under 35 USC 112, first paragraph for use of the term “non-pharmaceutical”. While this concept was believed inherent in the description of the ingestible composition, to distinguish from an injectable form of the composition, this term has been removed and the term “ingestible” substituted therefore which has ample support in the specification.

Claims 24-26 and 29-42 were rejected as being indefinite for use of the term “non-pharmaceutical”. As discussed above, this term has been deleted. However, the examiner should recognize that it is incorrect to state that “the agents must be placed in

pharmaceutical compositions for administration in vivo” as the inventors have established that these agents can be used directly, without further preparation, that is, the antibodies are found in the raw egg yolks, and can be administered by the ingestion of the raw egg yolks, as described in the specification.

There is no need to prepare a specific pharmaceutical preparation for administration, and as the experiments establish such oral ingestion of the raw egg yolk is in fact “more effective in reducing the overall body weight slightly and lowering the feed conversion rate very significantly.” P. 30, lines 16-20

In fact, this is an advantage and a quite surprising result of the invention, as discussed on page 32, lines 13-26 of the specification. Experiment 1 illustrated the significant titer of the raw egg yolk, not of an isolate or extract from the yolk, but the yolk itself, and experiment 1 proceeded using raw egg yolk, not a pharmaceutical preparation: P. 24, l. 6-9, 22-22; P. 25, l. 8-10; P. 26, l. 6, 17-23; P. 27, l. 1-3. The results establish “in vivo” effects by ingestion alone, superior to the effect of injection. Consequently, this rejection should be withdrawn.

Claims 24-26 and 29-42 were rejected as being obvious over Flint in view of Lee.

In order to uphold a finding of obviousness, there must be some teaching, suggestion or incentive for doing what the applicant has done. ACS Hospital Sys'ts. Inc. v. Montefiori Hospital, 723 F.2d 1572 (Fed. Cir. 1984). Also, “Both the suggestion and the expectation of success must be found in the prior art, not in the applicant's disclosure.” In re Dow Chemical Co., 837 F.2d 469 (Fed. Cir. 1988).

The Examiner has acknowledged that Flint does not mention egg laying animals for use in producing anti-adipocyte antibodies and further Flint does not indicate that anti-adipocyte antibodies can be orally administered. To the contrary, Flint teaches a method where serum is obtained from the blood of an animal, which must go through several processing steps before it is ready for administration “by injection of antibodies intraperitoneally or intravascularly. ...” Col. 2, l. 22-23

The preparation of the antibodies was described as follows:  
“2-year old Clun sheep were injected subcutaneously with 6 ml of

incomplete Freund's adjuvant (2 parts oil to 1 part aqueous phase) containing 250 .mu.g of purified rat adipocyte plasma membrane. The injections were repeated at 3-weekly intervals and blood was obtained 10-18 days after the third injection and again 10-18 days after subsequent boosts.

The blood was allowed to clot and then centrifuged at 2000 g for 20 min to obtain serum. A crude immunoglobulin fraction was prepared from the serum by precipitation in 45% NH.sub.4 SO.sub.4 and centrifugation at 2000 g for 30 min. The immunoglobulin-containing pellet was redissolved in 0.1M phosphate buffer pH 7.4 and dialyzed extensively to remove all traces of NH.sub.4 SO.sub.4. This material was stored at -20.degree. C. until used for injection into rats." Col. 3, l. 10-45

As such, Flint would lead a person skilled in the art away from even considering the use of egg-laying farm animals.

"A reference may be said to teach away when a person of ordinary skill, upon reading the reference, would be discouraged from following the path set out in the reference, or would be led in a direction divergent from the path that was taken by the applicant. The degree of teaching away will of course depend on the particular facts; in general, a reference will teach away if it suggests that the line of development flowing from the reference's disclosure is unlikely to be productive of the result sought by the applicant. See *United States v. Adams*, 383 U.S. 39, 52, 148 U.S.P.Q. 479, 484, 15 L. Ed. 2d 572, 86 S. Ct. 708 (1966) ("known disadvantages in old devices which would naturally discourage the search for new inventions may be taken into account in determining obviousness"); *W.L. Gore & Assoc., Inc. v. Garlock, Inc.*, 721 F.2d 1540, 1550-51, 220 U.S.P.Q. 303, 311 (Fed. Cir. 1983) (the totality of a reference's teachings must be considered), cert. denied, 469 U.S. 851 (1984); *In re Spinnoble*, 56 C.C.P.A. 823, 405 F.2d 578, 587, 160 U.S.P.Q. (BNA) 237, 244 (CCPA 1969) (references taken in combination teach away since they would produce a "seemingly inoperative device"); *In re Caldwell*, 50 C.C.P.A. 1464, 319 F.2d 254, 256, 138 U.S.P.Q. (BNA) 243, 245 (CCPA 1963) (reference teaches away if it leaves the impression that the product would not have the property sought by the applicant). *In re Gurley*, 27 F.3d 551, 553 (Fed. Cir. 1994)

Here, Flint would lead one away from the use of egg laying farm animals, and also away from ingestion, as opposed to injection. Simply, one reading Flint would not believe that the applicants' invention would work as effectively as it does.

A person of skill in the art would also be led away from the present invention by Lee as Lee is directed to antibody purification. "The present invention is a method for the purification of egg immunoglobulin including the steps of extraction with e.g. medium-chain fatty acids, and further purification with e.g. ultrafiltration and/or ion exchange chromatography and/or protein precipitation and/or gel filtration and/or desalting and/or drying." Col. 3, l. 52-57

Certainly there is nothing to teach or suggest the use of three animals in the preparation of the antibodies for oral ingestion, that is, a source animal, distinct from the target animal, with the antibodies obtained from eggs of an egg laying farm animal. Certainly, there is nothing to teach or suggest that the ingestion of antibodies obtained from or contained in egg yolk, would be more effective than administration by injection, as found by the present inventors.

There is no teaching or suggestion supporting the combination proposed by the examiner, and even if made, there is nothing to suggest that the applicants' invention would be achieved. Consequently, claim 24 and the claims depending therefrom are not rendered obvious by the combination, and this rejection should be withdrawn.

Based on the above amendment and remarks, favorable consideration and allowance of the application are respectfully requested. However should the examiner believe that direct contact with the applicant's attorney would advance the prosecution of the application, the examiner is invited to telephone the undersigned at the number given below.

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